



COMITÉ INTERPROFESSIONNEL DU VIN DE CHAMPAGNE

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852
USA

Epernay, December 18, 2003

Dear Sir/Madam,

**PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS
RESPONSE ACT 2002: COMMENTS ON INTERIM FINAL RULE**

Docket numbers: 02N-0276, 02N-0277, 02N-0278 (registration, record keeping, prior notice):

The Comité Interprofessionnel du Vin de Champagne and our US representatives, the Office of Champagne, USA, thank you for the opportunity to comment on the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 interim final rule. Our comments are directed toward a particular aspect of section 307 (prior notice), that, if not corrected, could affect the information submitted or used in sections 305, 306 and 307.

Of particular concern are the imprecise product codes that have been developed to identify products under this new arrangement. To fulfill the requirements, shippers will have to provide a code describing their product(s). In order to facilitate such product code definitions, the Food and Drug Administration developed the following website: <http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.cfm>. However, when one seeks to identify particular alcoholic beverages at this site, we observed that, among the different product names listed, it is possible to find the following:

- Champagne (B-04)
- Wine, Sparkling (Artificially Carbonated) (B-06)
- Wine, Sparkling (Naturally Carbonated) (B-05)

We have been unable to find any clear product definitions for these codes. At the same time, we have found no clear matches in the Code of Federal Regulations (chapter 27) for the FDA designations listed above.

For example, the definition for "carbonated grape wine" (27 CFR Chi. 1, §4.21c) does not provide any distinction between "artificially carbonated" and "naturally carbonated." Hence, one could surmise that, pursuant to such a definition, a "carbonated wine" is by definition an "artificially" carbonated wine as it is made effervescent by adding exogenous carbon dioxide. This is clearly not the case for all sparkling wines.



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We believe that the inclusion of these undefined terms could lead to incomplete or erroneous use of the product code "B-04 - Champagne" because it could be interpreted to mean those sparkling wines which benefit from the appellation of origin "Champagne." Such lack of clear definition could also lead some to mistakenly use the product code "B-04 - Champagne" for other sparkling wines - when these wines are not entitled to use such an appellation - due to the unclear definition of "carbonated wines," as described above.

In the latter case, the interim rule would allow an unacceptable misuse of the name "Champagne" which is a French appellation of origin, protected under European Union law. In addition, it is important to stress that U.S. regulations (see 27 CFR Ch. 1, § 4.24 b.1 et 24.257 c) do not allow this name to be used as a product designation.

Consequently, we request that the Food and Drug Administration modify the product name related to the code B-04 to identify the products appropriately, for example, "sparkling wines". Alternatively, we would respectfully suggest that the B-04 designation be reserved for Champagne as defined by EU law, while B-05 could be used for "sparkling wines" and B-06 for "carbonated wines".

Many thanks for your attention to this matter and for the opportunity to provide comment. We hope that you will amend your rules to protect the name Champagne appropriately and garner the correct information under the interim rule.

If we can be of any further assistance, please do not hesitate to contact me or Mr. Thomas Bruce of the Office of Champagne, USA, at 202.777.3527.

Respectfully,

Le Secrétaire Général

Nicolas OZANAM

CC: European Commission